REMARKS

In the Office Action mailed on November 27, 2002, the Examiner communicated a number of rejections. Claims 1-9 and 12-15 were at issue. Claims 1-9 and 12-15 were rejected. The Examiner made the following rejections:

I. The Examiner rejects Claims 1, 2, 4-9 and 13, under 35 U.S.C. § 102(b), as allegedly being anticipated by Caruso (U.S. Patent 6,043,244). In addition, the Examiner rejects Claims 1, 2, 4-9 and 12-15, under 35 U.S.C. § 102(b), as allegedly being anticipated by Plachetka (U.S. Patent 5,872,145).

II. The Examiner rejects Claim 3, under 35 U.S.C. § 103(a), as allegedly being unpatentable over Caruso (U.S. Patent 6,043,244) or Plachetka (U.S. Patent 5,872,145).

I. The Cited Art CANNOT Anticipate The Invention as Claimed

Applicant must protest the Examiner's non-final[1] rejection as unsupported and unwarranted. In the previous Response, the Applicant amended the claims to a "closed" format by introduction of the term "consisting." The Examiner makes no mention of this amendment in the Office Action mailed 11/27/03. While the Examiner indicates that Applicant's arguments "have been considered," the Examiner does not acknowledge the impact of the closed format in the claims. MPEP 2111.03 notes that:

> "The transitional phrase 'consisting of' excludes any element, step, or ingredient not specified in the claim."

See also, In re Gray, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("consisting of" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.").

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[1] While the Examiner checked the box "FINAL," the text of the action noted "Due to the new grounds of rejection, this action is deemed non-final." A phone call to the Examiner confirmed the non-final nature of the action.

By excluding other active ingredients, the claims CANNOT be anticipated by art that contains more than one active ingredient. In this regard, the Examiner has characterized the art as follows:

1. "Caruso teaches a method treating migraines wherein dihydroergotamine is administered with an antimigraine-potentiating amount of an NMDA receptor antagonist." and,

2. "Plachetka teaches a method of treating migraines wherein an effective amount of 5-HT agonist and NSAID are administered to a patient."[2]

Antagonists and agonists are active ingredients. Thus, both Caruso and Plachetka teach two active ingredients. As such, they CANNOT anticipate the claims. The Applicant, therefore, respectfully requests the Examiner withdraw the pending 102 rejection.

II. The Claims Are Not Obvious Under 35 U.S.C. § 103(a)

Claim 3 stands rejected as allegedly unpatentable over Caruso *or* Plachetka. The Examiner states:

> "[i]t is the position of the Examiner that any form of DHE would be effective in treating migraines. No criticality is seen in DHE being in the form of a base. Applicants have not shown any unexpected results from the base form."[3]

Applicant reminds the Examiner that **all** claim limitations must be considered and given weight. *In re Saether*, 181 USPQ 37, 39 (CCPA 1974) (reversing the Board on 103). The Examiner is speculating - without support in the record - that there are no advantages. However, in numerous places in the specification, Applicant has taught why, in some embodiments, the administration of the base form of DHE is advantageous. Specifically, the Applicant, in the application as filed, notes:

> "A sublingual formulation of DHE in the base form of the drug would permit the use of lower doses of DHE since a greater portion of the medication would be absorbed directly into the blood stream thereby allowing a direct route to the afflicted target area."[4]

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[2] Office Action mailed 11/27/02, pp. 2- 3.

[3] Office Action mailed 11/27/02, page 4.

[4] Application as filed, page 3, ll. 27-30.

and,

> "Although the present invention is not limited to any particular mechanism, it is believed that the adjustment of the pH of the environment of the sublingual area will convert the administered DHE to the readily absorbable DHE base."[5]

Importantly, both Caruso and Plachetka are completely silent on the incorporation of a pH modulating agent which can alter the microenvironment in the area of administration (e.g. in one example the sublingual mucosa) such that the base form of DHE is favored over the far less absorbable mesylate salt.

The Examiner is reminded that the Patent Office is not free to deny patentability of claims where the only reason is speculation by the Examiner. In the face of the advantages taught in the specification, the Examiner must come up with actual evidence rebutting the advantages - not mere speculation. Moreover, technical assertions by the Examiner must be supported by references or an affidavit.

The requirement that the Examiner make a showing of a suggestion, teaching or motivation is "an essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998). There are three sources for this evidentiary component: the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996). The suggestion most often comes from the teachings of the pertinent references. *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998). Nonetheless, regardless of the source of the requisite evidence, the Examiner's showing "must be clear and particular, and broad conclusory statements . . . standing alone, are not 'evidence'." *In re Dembiczak*, 175 F.3d 994, 1000 (Fed. Cir. 1999).

It is the Examiner's burden to present "evidence" and this showing must be "clear and particular." Importantly, since an Examiner is NOT one skilled in the art (under the law), the Examiner's opinion on what one skilled in the art might believe is of no moment. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) ("[T]he examiner's assumptions do not constitute the disclosure of the prior art.").

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[5] Application as filed, page 4, ll. 21-23.

Of course, if the Examiner has knowledge of relevant facts which are used to make the rejection, the Examiner is free to used those facts - but only if submitted in the form of an affidavit. *See* 37 CFR 1.107(b). In the present case, the Examiner has submitted no such affidavit.

In sum, the Examiner only provides opinion and conclusory statements in support of the pending obviousness rejections. These opinions and conclusions may not be considered "evidence" and are inadequate to sustain a rejection under 35 U.S.C. § 103. Accordingly, the claims are not obvious and should be passed to allowance.

CONCLUSION

The Applicant believes that the arguments set forth above traverse the Examiner's rejections and, therefore, requests that all grounds for rejection be withdrawn for the reasons set above. Indeed, this response has been necessitated by the (apparent) failure of the Examiner to properly consider the "consisting" language of the claims (introduced in the prior response). Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect at 617.252.3353.

Dated: May 23, 2003

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APPENDIX I
CLEAN VERSION OF THE ENTIRE SET OF PENDING CLAIMS PURSUANT TO 37 CFR § 1.121(c)(3)

1. A method of treating migraines, comprising:

a) providing i) a patient having one or more symptoms of a migraine and ii) a formulation consisting of one active ingredient and one or more inactive ingredients, wherein said active ingredient is dihydroergotamine;

b) administering said formulation to said patient sublingually under conditions such that said one or more symptoms of said migraine are reduced.

2. The method of Claim 1, wherein said dihydroergotamine is a pharmaceutically accepted salt.

3. The method of Claim 1, wherein said dihydroergotamine is a pharmaceutically accepted base.

4. The method of Claim 1, wherein said sublingual administration is via a liquid.

5. The method of Claim 4, wherein said liquid is administered by a spray.

6. The method of Claim 4, wherein said liquid is administered by drop.

7. The method of Claim 1, wherein said sublingual administration is via a paste or gel.

8. The method of Claim 1, wherein said sublingual administration is via a tablet or compressed powder.

9. A method of treating migraines, comprising:

a) providing i) a patient having one or more symptoms of a migraine and ii) a formulation consisting of first and second active ingredients and one or more inactive ingredients, wherein said first active ingredient is dihydroergotamine and said second active ingredient is selected from the group consisting of analgesics and anesthetics;

b) administering said formulation to said patient sublingually under conditions such that said one or more symptoms of said migraine are reduced.

12. The method of Claim 1, wherein the sublingual administration is via a fast dissolve formulation.

13. The method of Claim 1, wherein one of said inactive ingredients is an effervescent agent.

14. The method of Claim 1, wherein one of said inactive ingredients is an pH adjusting agent.

15. A method of treating migraines, comprising:

a) providing i) a patient having one or more symptoms of a migraine and ii) a fast dissolve formulation consisting of one active ingredient and one or more inactive ingredients, wherein said active ingredient is dihydroergotamine one of said inactive ingredients is a pH adjusting agent;

b) administering said formulation to said patient sublingually under conditions such that said one or more symptoms of said migraine are reduced.